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10/663,014

09/15/2003

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07/29/2008

EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |   |   |  |
|------------------------------|---|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/663,014        | <b>Applicant(s)</b><br>KRAUSS, ACHIM H. |  |
|                              | <b>Examiner</b><br>Lakshmi S. Channavajjala | <b>Art Unit</b><br>1611                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

Receipt of amendment and remarks all dated 5-5-08 is acknowledged.

Claims 1-10 and 12-15 are pending.

1. Upon careful consideration, the rejection made in the last office action dated 5-5-08 has been withdrawn and the following new rejection has been applied:

***Double Patenting***

2. Claims 1-10 and 12-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7,351,404. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims and the instant claims recite a composition that has the same active agent i.e., cyclopentane heptanoic acid compounds, particularly, the specific compound, bimatoprost. While instant claims recite a method of converting grey hair on beard or scalp to the original pigment in hair follicles, the patented claims recite a method of stimulating hair growth or converting vellus hair or intermediate hair to growth as a terminal hair, by employing the same compound and composition as that of the instant. Even though the patented claims do not recite the claimed conversion of grey hair to original pigment, the property is inherent to the composition of the patented claims. Thus, a skilled artisan applying the patented composition would not only observe hair growth stimulation but also conversion of grey hair to original pigment. Thus, the patented claims anticipate the instant claims.

3. Claims 1-10 and 12-15 are directed to an invention not patentably distinct from claims 1-16 of commonly assigned .S. Patent No. 7,351,404. Specifically, as explained above the patented claims recite the same composition as that of the instant application, in the same amounts and in the same form i.e. as topical creams, lotions, etc. Hence, even though the patented claims do not recite the claimed method of

converting the grey hair to original color, the claimed method is inherent to the method of the patented claims.

4. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. 7,351,404, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-10 and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US 7,351,404 to Woodward et al (Woodward).

The applied reference has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Woodward et al teaches instant composition and topical application of the same to enhance hair growth. The compounds and the compositions described by Woodward et al are the same as that of the instant application (see col. 4-6). The compositions have the same amounts or percentages (col. 9, L 10-23) and administered as the same formulations as that claimed i.e., creams, ointment, aerosol etc., (see examples). In addition to stimulating the hair growth on skin, Woodward also states that the claimed compound enhances hair growth on scalp and increases pigmentation at the site of the treatment (col. 7, L 59-67 and col. 8, L 6-10). Thus, even though Woodward fails to explicitly state the claimed method of converting grey hair on beard or scalp to its original pigment, the claimed method is inherent to the teachings of Woodward because

the composition and the method of applying the composition taught by Woodward are the same as that claimed.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article New drugs of 2001 (J Amer. Pharm. Association 2002) in view of US 7,351,404 to Woodward et al (Woodward) or unpatentable over the article New drugs of 2001 (J Amer. Pharm. Association 2002) in view of US 5,290,562 ('562, cited in previous actions of record) and Report of National Institute of Neurological Diseases and Stroke (NINDS).

The above article entitled "new Drugs of 2001" discloses two new drugs for glaucoma, bimatoprost and travoprost of which the former is within the scope of the instant claims (see claim 4). The article teaches that the compound bimatoprost is useful in reducing the intraocular pressure (page 2). However, the side effects of the compound included among others, darkening of eyelashes, eyelash growth and pigmentation (page 3). Thus, the compound of the instant invention is known for increasing the pigmentation and darkening of hairs (eye lashes). The article also teaches 0.3% bimatoprost (claim 2) as a solution (claim 9). While the above article fails to teach the claimed method per se, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ bimatoprost for increasing

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pigmentation or darkening hair (eyelash or beard or scalp hair) because the compound bimatoprost is known to increase pigmentation.

A careful review of the instant specification on page 7, lines 10-18 states:

“As used herein, gray hair includes hair associated with the scalp, eyebrows, eyelids, beard, and other areas of the skin of animals, e.g. humans”. Thus, the ability of bimatoprost in converting gray hair to original pigment is not dependent upon on the hair location (beard or scalp or eyelash). The above article fails to teach various routes of administration claimed in the dependent claims.

The teachings of Woodward have been discussed above. In particular, examples 3, 4 and 6-10 teach applying the composition containing the active agents such as tegacid, spermaceti or bimatoprost to scalp and skin. Thus, Woodward suggests applying instant composition on the same sites as that claimed in the instant and therefore it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to expect conversion of grey hair to original color of the hair follicle at the site of application of the composition, in addition to increasing the hair growth, because Woodward employs the same composition as that of the instant, which applicants described as effective in converting grey hair to original pigment and further Woodward suggests that the compounds also exhibit increased pigmentation of the hair (col. 8).

'562 teach a method of increasing melanin formation on the skin or scalp by administering a melanin synthesis promoting or a pigmenting compound i.e., a tyrosine or its derivative. '562 teach that increasing the melanin synthesis in the skin damaged



by UV radiation can be induced by melanin synthesizing compounds (co1.1-2) and that the pigment activity is also increased in the scalp.

NINDS reports old drugs with new uses, particularly with cholesterol-lowering such as statins that are commonly used for heart attack. NINDS report states that statins are commonly employed in treating heart attack and stroke, are also effective in treating Multiple Sclerosis and other immune disorders. The report of NINDS shows that it is not uncommon in the art of pharmaceuticals and medicine to identify new uses for old drugs having different utility. In this regard, "new Drugs of 2001" discloses lengthening of lashes and their pigmentation for the claimed drugs (of the instant invention) that are otherwise employed for treating glaucoma. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the composition containing bimatoprost of "new drugs 2001" article for retarding the appearance of grey hair in a mammal in need thereof because '562 teaches that increasing or stimulating melanin synthesis improves the retardation of grey hair together with increasing the melanin pigment and NINDS report shows using a single drug for multiple treatments or applications. Further, in the absence of any criticality, choosing a particular route of administration of bimatoprost so as to achieve the desired pigmentation would have been within the scope of a skilled artisan.

### ***Response to Arguments***

Applicant's arguments filed 5-5-08 have been fully considered but they are not persuasive.

Applicants argue that glaucoma treatment is carried out by an ophthalmologist as opposed to dyeing gray hair is the work of a cosmetician, not an ophthalmologist, which is an important distinction in finding the instant obvious because the two fields are non-analogous and a cosmetician is not familiar with using eye drops. This argument is not persuasive because it is clear from the teachings (particularly examples) of Woodward et al that the same bimatoprost composition (known for glaucoma treatment) can be used successfully used for scalp as well as eyelashes. NINDS report further supports that multiple uses or utilities for a single drug, identified at different time periods, is not uncommon. Thus, while an ophthalmologist would look for glaucoma effective amounts and routes of administration of bimatoprost, a cosmetician would readily be able to apply the same composition to skin and scalp and expect the hair growth stimulation, as well as instant method of converting grey hair to original color because the same compounds exhibit all the above properties or activities. The teachings of Woodward are in contrast to the argument that the articles Hormone Research 2000; 54-243-250 and Hair Science: How and Why hair grows, shows that eyelashes are not equivalent to scalp hair, and only supports examiner's position stated in the previous action i.e., Instant specification on page 7, lines 10-18 states:

"As used herein, gray hair includes hair associated with the scalp, eyebrows, eyelids, beard, and other areas of the skin of animals, e.g. humans". Thus, the ability of bimatoprost in converting gray hair to original pigment is not dependent upon on the hair location (beard or scalp or eyelash). Accordingly, bimatoprost possess the ability to darken eyelashes and also the hair on scalp or beard.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/  
Primary Examiner,  
Art Unit 1611  
July 18, 2008